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Effect of *Musa acuminata* Starch concentration on the Disintegrant Activity of Paracetamol Tablets

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ABSTRACT

Today, tablets are one of the most widely used pharmaceutical dosage forms. Both active pharmaceutical ingredients (API) and inactive ingredients such as disintegrants are found in pharmaceutical dosage forms. Disintegrants are essential for dissolving the tablet into small particles and increasing the surface area of the API when it is exposed to gastrointestinal fluids. As a result, choosing the right type and concentration of disintegrant is often the most important aspect in determining tablet quality. Effect of *Musa acuminata starch* concentration on the disintegrant activity of paracetamol tablets was now researched on. Starch from unripe banana fruits was extracted with distilled water and 0.05M sodium hydroxide. Banana starch powder at concentrations of 5, 10 and 15% w/w were used to formulate paracetamol tablets by direct compression. Starch powder and tablet properties were evaluated. Increase in concentration of banana starch powder from 5-15% w/w led to a decrease in disintegration time, weight variation, and an increase in friability. The tablets formulated from banana starch at all concentration were comparable to tablet properties in the standard BP 2009. The starch powder pH, true density, bulk density, tapped density, angle of repose, Hausner's ratio and Carr's index were 6.57, 1.51g/ ml, 0.55g/ml, 0.61g/ml, 32.3°, 1.11 and 9.90, respectively. The tablets exhibited disintegration time, weight variation, thickness, and friability values ranging from 0.55-0.44min, 1.66-0.59%, 4-3.39mm, 0.13-0.55%, respectively. The tablets met acceptable Pharmacopoeia requirements at starch concentration studied. Results revealed that banana starch could be used as a disintegrant in paracetamol tablet formulation due its comparable properties with the standard BP 2009 specifications. *Musa acuminata* starch when used at concentration of 15% gives optimum disintegrant activity.
Keywords: *Musa acuminate,* Starch concentration, Disintegrant, Paracetamol tablets

INTRODUCTION

Today, tablets are one of the most widely used pharmaceutical dosage forms. Both active pharmaceutical ingredients (API) and inactive ingredients are found in pharmaceutical dosage forms (excipients). The API's compression characteristics information is quite valuable. As a result, brittle excipients should be used if the API is high dosage and possesses plastic deformation (e.g. lactose). Plastic excipients are recommended for brittle or elastic drugs (e.g. microcrystalline cellulose) [1-4]. Deformation (particles changing shape) occurs when the compressive force on the particles is increased. An elastic deformation occurs when the stress is relieved and the deformation entirely vanishes (returning to its original shape) [5-11]. A plastic deformation occurs when a stress is released but does not totally vanish. The fact that plastic deformation is followed

by material breaking is a feature of brittle materials Most tablet formulations contain a disintegrant, which is essential for dissolving the tablet into small particles and increasing the surface area of the API when it is exposed to gastrointestinal fluids [12-18]. As a result, choosing the right type and amount of disintegrant is often the most important aspect in determining tablet quality, even though particle size, shape, and packing geometry of disintegrant in a tablet must also be considered [19-24]. The deformation is determined by the particle characteristics [25-29]. The appropriate disintegrant selection is a critical phase that necessitates numerous laboratory tests in order to produce a tablet formulation based on the formulator's expertise and experience. When a compressed tablet is swallowed, it disintegrates mechanically into small grains. It is defined by the dissolution of inter-particulate linkages formed during tablet compression Disintegrant, on the other hand, is an excipient in a normal tablet dosage form that ensures that the tablet matrix breaks up during ingestion. They work through many processes, and a variety of circumstances can influence their effectiveness [6]. Particle size, disintegrant source, disintegrant type, and disintegrant concentration are examples of such parameters. Swelling is the most widely accepted mode of disintegrant action, which involves dimensional amplification, in which particles increase to push apart contiguous components, causing the tablet matrix to break up [8]. Corn and potato starches, cation-exchange resins, alginic acid, agar, bentonite, natural sponge, guar gum, citrus pulp, methylcellulose, carboxymethylcellulose, and various other forms of starch are all frequently used in tablet formulation [12]. Formulators should understand how disintegrants act in order to identify better disintegrants and generate more optimized formulations [8]. The East African Highland banana (*Musa acuminata*) is a starch banana cultivar that originated in the African Great Lakes [11]. According to Tanzanian Statistical Abstract, (2017), Uganda and Tanzania rely on *Musa acuminata* as a staple food. According to Hamilton et al. (2016), cooking bananas, brewing bananas, dessert bananas, roasting bananas, and unique red bananas are among the banana varieties found in Uganda. However, the most common banana farmed in Uganda is the cooking banana (*Musa acuminata*).

Bananas are high in fiber, potassium, vitamin B6, vitamin C, as well as antioxidants and phytonutrients such as starch [9]. According to a study conducted by a food scientist Umar Mutuya as cited by [16] banana is 75% water and 25% starch. Unripe bananas (green bananas) have a higher starch content (about 80% dry weight) than ripe bananas [13]. This high starch content in bananas can be removed and used as excipients in the production of paracetamol tablets. Paracetamol, often known as acetaminophen, is an aniline derivative that is widely used as an antipyretic and analgesic over-the-counter (OTC). Because of its limited anti-inflammatory effect, it is rarely classed as a non-steroidal anti-inflammatory medicine (NSAID). N-(4-hydroxyphenyl) acetamide is its IUPAC name [9]. According to [15], maize starch, gelatin, silica, talc, sodium starch glycolate, and magnesium stearate are some of the excipients used in the production of starch. Disintegration time and drug release rate from tablet formulations are affected by a number of factors. Temperature, pH, moisture content, particle size, compression force, disintegrant type, and disintegrant concentration are all factors to consider. However, the concentration of *Musa acuminata* starch at which there is maximum disintegration is not well ascertained. This study therefore aims to determine the effect of concentration on the disintegration time of paracetamol from non-granulated banana starch so as to determine the concentration of starch at which there is maximum disintegration.

Aim of the study

The aim of this study was to determine the effect of banana (*Musa acuminata)* starch concentration on the disintegration time of paracetamol tablets.

MATERIALS AND METHODS

Paracetamol was obtained from Kampala International University Pharmaceutics laboratory.
Banana starch was obtained from green unripe edible banana (*Musa acuminata)* obtained from Ishaka market. Other raw materials were also obtained from Kampala International University Pharmaceutics laboratory.

Study Design

An experimental design was used in this study. It involved formulation of different paracetamol tablets containing various concentrations of ungranulated banana starch by direct compression. The disintegration times of various tablets were determined using standard methods described in the British pharmacopoeia.

Extraction of Starch from *Musa Acuminata.*

The starch extracted from *Musa acuminata* was extracted using standard method. Fresh bananas were peeled and properly cleaned in distilled water. Using a sharp knife, the peeled banana was sliced into small pieces, placed in the mixer, and blended with 0.05M sodium hydroxide. After that, the slurry was sieved. The filtrate was allowed to settle for one hour before being collected and washed many times with distilled water to completely eliminate the alkali. The starch was then dried in a hot air oven at 60°C for 6 hours. After that, the starch was sieved and stored in an airtight container.

The percentage yield of starch was then calculated from;

$$Percentage\ yield = \frac{weight\ of\ starch}{Weight\ of\ the\ peeled\ banana} x100$$

The percentage yield was calculated as 2.24%

Pre-Formulation Studies of Starch Powder.

pH

5.0g of starch were added to 25ml of distilled water followed by shaking for 1 minute. The solution was allowed to settle for 15minutes and the pH of the starch solution determined using a pH meter

True density

Fluid displacement was used to determine the real density of the starch. The weight of an empty 20 ml measuring cylinder was recorded before it was filled with pure water. W_3 was the weight of the fluid that filled the cylinder. Approximately 5 ml of the fluid was removed from the cylinder, and 0.5 g of starch (W_2) was added.
The true density was then calculated using the relation;

$$True\ density = \frac{W^2\ W^3}{50(W2 - W4 + W3)}$$

Bulk Density

In a 25 ml measuring cylinder, I0 g of starch powder was added. The volume was measured after carefully flattening the upper surface. Bulk density was calculated from;

$$\text{Bulk density (Pb)} = \frac{\text{weight of microcapsules (g)}}{\text{Bulk volume (ml)}}$$

Tapped density

On a padded bench, the I0 g starch powder was softly tapped 150 times, and the final volume was recorded. Tapped or final bulk density was then calculated using the relation:

$$Tapped\ density\ (\text{Pt}) = \frac{\text{Weight of Microcapsules (g)}}{\text{Tapped volume (ml)}}$$

Angle of repose

The tip of a funnel was clamped over a 9 cm wide petri dish. After that, the starch powder was allowed to flow through the funnel until the apex of the cone just brushed the funnel's tip. The average diameter (D) and height (h) of the powder cone's base were measured. Using the relationship, the angle of repose (β) was computed.;

$$Tan\beta = \frac{2h}{D}$$

Hausner's ratio

This was obtained as the ratio of tapped density to bulk density of the starches.

$$Hausner's\ ratio = \frac{Tapped\ \ density}{Bulk\ density}$$

Carr 's compressibility index

Carr's index was calculated from the bulk and tapped density data using the relation:

$$Carr's\ index = \frac{Tapped\ density - Bulk\ density}{Tapped\ density}\ x\ 100\ Carr$$

Formulation of Paracetamol Tablets by Direct Compression.

The same formula as above was used to formulate paracetamol tablets with varying *Musa acuminata* starch concentration. All the formulation components were mixed in their respective proportions using a mortar and a pestle and compressed using a single punch machine with a weight fill of 75mg to form paracetamol tablets.

Table 1: Formulation ingredients

Ingredient	**Quantity per tablet**		
	5%w/w starch	**10%w/w starch**	**15% w/w starch**
Paracetamol powder (mg)	61.5	57.75	54
Banana starch powder (disintegrant)(mg)	3.75	7.5	11.25
Maize starch 5%w/w (binder) (mg)	3.75	3.75	3.75
Maize starch 7.5% w/w (diluent)(mg)	11.25	11.25	11.25
Magnesium stearate 0.5%w/w (lubricant)(mg)	0.375	0.375	0.375
Total tablet weight (mg)	**75±3.75**	**75±3.75**	**75±3.75**

Quality Control Tests for Tablets

Disintegration time test

The disintegration time test was carried out utilizing an Erweka ZT 120 basket and rack assembly, 0.1 M Hydrochloric acid as the disintegration medium, and 37.0 1.0°C as the operating temperature. The test was conducted using 6 tablets from each concentration, and the process was carried out according to the BP guidelines (2009).

Friability test.

From each concentration of tablets used in the study, six (6) tablets were chosen at random. The tablets were first powdered and weighed, with the weight W_0 being recorded. The tablets were then placed in the friabilator's drum, which was rotated at a speed of 25rpm for four minutes. The tablets were taken out of the friabilator, dedusted, and reweighed, with the weight W_1 recorded. The friability of the tablets was calculated from the formula:

$$Friability) (\%) = \frac{W0 - W1}{W_0} x100$$

Where, $\mathbf{W_0}$ and $\mathbf{W_1}$ are the initial and final weights of the tablets respectively.

RESULTS

Results of Pre-Formulation Studies for Starch Powder

Table 2: Results of pre-formulation studies for banana starch powder

TEST	RESULTS
pH	6.57
True density(g/ml)	1.51
Bulk density(g/ml)	0.553
Tapped density(g/ml)	0.614
Angle of repose	32.3^0
Hausner's ratio	1.11
Carr 's compressibility index (%)	9.90

The pH of *Musa acuminata* starch was 6.75.

The true density of the starch powder was 1.51 g/ml.

The bulk density of the starch powder was 0.553 g/ml.

The tapped density of *Musa acuminata* starch was 0.614 g/ml

The angle of repose of *Musa acuminata* starch was 32.2^0

The Hausner's ratio of *Musa acuminata* starch was 1.11

Musa acuminata had a Carr 's compressibility index of 9.90%.

Quality Control Test Results.

Table 3: Quality control test results for tablets from non-granulation formulation

Starch Concentration (%)	Tests			
	Disintegration time (min)	Friability (%)	Thickness (mm)	Weight Variation (%)
5%	0.55	0.13	4	1.66
10%	0.5	0.35	4.1	0.72
15%	0.44	0.55	3.9	0.59

The disintegration time of the tablets decreased with increase in *Musa acuminata* starch concentration (from 0.55-0.44 minutes for 5%-15% starch concentrations respectively). The friability of paracetamol tablets decreased with increase in starch concentration (from 0.13% to 0.55% for 5%-15% starch concentrations respectively). The average tablet thicknesses were 4, 4.1 and 3.9 mm for 5, 10, and 15% starch concentrations respectively. The weight variations of the tablets were 1.66%, 0.72% and 0.59% for 5%, 10% and 15% starch concentrations respectively.

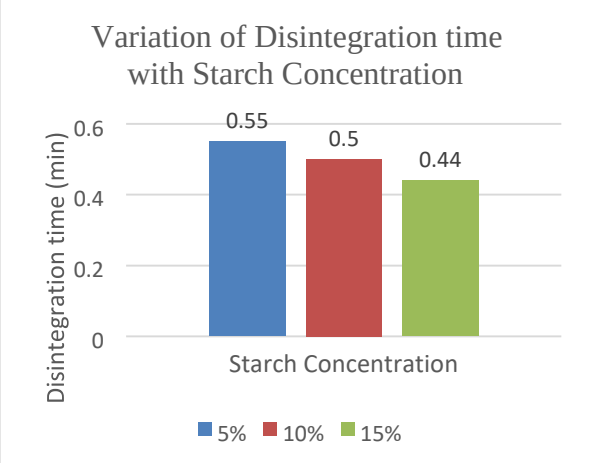

Figure 1 Starch concentration versus disintegration time from granulation formulation

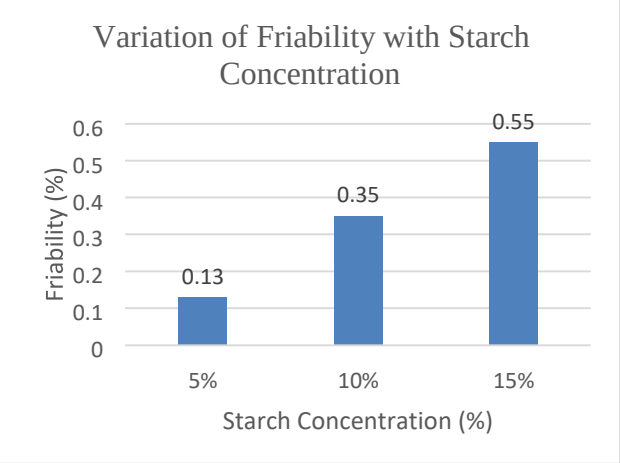

Figure 2 Starch concentration versus friability from non-granulation formulation

Table 4: Relationship between the various starch concentrations

		Disintegration Time (Mins)	Friability (%)	Thickness (mm)	Weight Variation (mg)
Disintegration Time (Mins)	Pearson Correlation	1	-.997* .025	.545	-.595
	Sig. (1-tailed)			.317	.297
	N	3	3	3	3
Friability (%)	Pearson Correlation	-.997* .025	1	-.476	.657
	Sig. (1-tailed)			.342	.272
	N	3	3	3	3
Thickness (mm)	Pearson Correlation	.545	-.476	1	.350
	Sig. (1-tailed)	.317	.342		.386
	N	3	3	3	3
Weight Variation (mg)	Pearson Correlation	-.595	.657	.350	1
	Sig. (1-tailed)	.297	.272	.386	
	N	3	3	3	3

*. Correlation is significant at the 0.05 level (1-tailed).

DISCUSSION

Characterization of *Musa Acuminata* Starch Powder

The pH of *Musa acuminata* starch powder was 6.57 which was slightly acidic but remained within the normal recommended limits of 4-7 as stated in the British Pharmacopoeia. The angle of repose of *Musa acuminata* starch powder was 32.2^0. According to the BP specifications, a powder is considered to have good flow properties if its angle of repose is between 25-40^0. It is generally considered that the powders with angle of repose of less than about 40^0 are free flowing while those exhibiting repose angle of 50^0 and more are likely to cause flow problems (Jan et al., 2016) . Thus, an angle of repose of 32.2^0 indicated that *Musa acuminata* starch had good flow properties and could be used in the manufacture of tablets.

Musa acuminata starch was found to have a compressibility index of 9.90%. According the BP (2009), powders with the compressibility index of ≤10% have excellent flowability and compressibility. Thus, *Musa acuminata* starch had excellent compressibility and flowability and can be easily compressed to form tablets. The Hausner's ratio of *Musa acuminata* starch powder was 1.11. According to the BP specification, a Hausner's ratio of 1.00-1.11 is an indicator of excellent flowability and compressibility. Thus, *Musa acuminata* starch powder was considered passable and could be used in tablet manufacture.

Quality Control Tests

The results obtained showed that increase in banana starch concentration decreased the disintegration time of the tablets. The tablet disintegration time results presented in **Tables 3 and 4** show that all the tablets complied with the BP (2009) specifications for uncoated tablets, where the tablets should disintegrate within 15 minutes. Tablet disintegration times ranged between 0.44 and 0.55 minutes for

concentrations 5% to 15% respectively. A study conducted by [7] showed that increase in concentration of starch decreased the disintegration time of tablets. This was because increase in starch concentration increased water wicking into the tablet matrix which caused disaggregation of the matrix particles hence faster disintegration. The results of friability obtained (**Table 3*)*** showed that all the tablets passed the friability test since their respective friability test results ranged from 0.13% to 0.55% which complied with the BP specification of ≤2% for tablets formulated by direct compression. The results further showed that increase in banana starch concentration resulted into an increase in the friability of the tablets. This was because an increase in starch concentration decreased the tablet hardness which made the tablet more friable. Results obtained in a study conducted by [11] showed that increasing the starch concentration resulted into an increase in friability of the paracetamol tablets.

CONCLUSION

From this study, it can be concluded that *Musa acuminata* ungranulated starch powder could be effectively used as a disintegrant in the manufacture of paracetamol tablets. The starch has proven to be a substitute for the standard disintegrants due to its remarkable disintegrant properties, can easily be produced on commercial scale since its readily available and affordable. In addition, extraction is easy and cheap although the yield is not very high.

Recommendations

The percentage yield of starch was low. This could in part be attributed to the extraction method used. Therefore, more research should be done to identify extraction methods that would give a greater yield of starch. Furthermore, more studies are needed to find out the compatibility of *Musa acuminata* starch with different active ingredients.

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APPENDICES

Appendix 1: Photographic Presentation of Materials and Methods

Peeling banana (*Musa acuminata*) for Starch extraction.

Peeled banana (*Musa acuminata*) for starch extraction

Musa acuminata starch settling

Harvesting of settled starch

Weighing Peeled banana (*Musa acuminata*)

Extracted banana starch

Formulated tablet from *Musa acuminata*

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